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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/753,738	01/02/2001	Geng Zhang	279.E71US1	3767

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EXAMINER	
SCHAETZLE, KENNEDY	

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
01/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/753,738	ZHANG ET AL.	
	Examiner	Art Unit	
	Kennedy Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52,53,56-59 and 64-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52,53,56-59 and 64-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 65 and 66 are objected to because of the following informalities: use of the word "when" in indent (c) of claims 65 and 66 is confusing. The examiner will assume the applicants intended to use the word "wherein." Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 52, 53, 59, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. (Pat. No. 5,265,602).

Regarding claim 64, Anderson et al. disclose a method of automatically determining whether an electrical stimulus evokes a response in the heart when the stimulus is applied by a cardiac electrical stimulation system having atrial and ventricular leads, a pulse generator, and a sensing circuit (see col. 2, lines 8-20), said method comprising the steps of:

(a) providing an electrical stimulus to at least one of an atrium or ventricle of a heart (see for example, col. 4, lines 18-21);

(b) attenuating afterpotential associated with said electrical stimulus (see col. 2, lines 45-56 and col. 4, lines 21-31);
(c) selectively sensing an evoked response by the heart to the electrical stimulus, wherein a signal associated with an evoked response from the electrical stimulus is sensed between electrodes selected from the group, including atrial electrodes and ventricular electrodes of said leads wherein one of said electrodes selected is an atrial electrode and one of said electrodes is a ventricular electrode (see col. 4, lines 21-31); and
(d) wherein said atrial lead includes an atrial tip electrode and an atrial ring electrode, and said ventricular lead includes a ventricular tip electrode and a ventricular ring electrode (see Figs. 1 and 3).

While Anderson et al. do not disclose the use of a ventricular lead comprising a coil electrode, it is taught that the particular type of lead selected is not critical to the invention (see col. 5, lines 8-16). Clearly the use of leads with coil electrodes are old and well known in the art. The examiner takes Official Notice to this effect. Coil electrodes provide greater surface areas and thus are suitable for use in high energy defibrillation systems. Depending on the individual under treatment, a lead combining both tip, ring and coil electrodes may be necessary when it is desirable to combine pacing with defibrillation. Such leads and devices are ubiquitous in the cardiac therapy arts.

Regarding the attenuation of afterpotentials, the examiner considers the system of Anderson et al. to reduce the amount of afterpotential occurring at the amplifier sensing input by using different electrodes to sense and pace (see for example col. 4, lines 24-31).

Regarding claim 65, all comments made above in the rejection of claim 64 apply here as well (likewise, comments made below regarding limitations similar to those found in claim 64 can also be applied to the rejection of claim 64 above). In addition, one can consider the "afterpotential attenuation device" to relate to that portion of the Anderson et al. invention that instructs the system to switch in the ring electrodes for

sensing (see for example the switching circuitry of Fig. 3), or for isolating the sensing amplifier during pacing. Claim 65 does not invoke 112, 6th paragraph. The requisite control circuitry is considered to be electrically coupled to the stimulation system in order to effect control of pacing therapy.

Regarding dependent claims 52 and 53, as is old and well known in the art, unipolar pacing such as described in col. 1, lines 50-59, occurs between tip electrodes and an indifferent housing electrode.

Regarding claim 59, the examiner takes Official Notice that the use of superior vena cava electrodes in pacing/defibrillating systems is old and well-known. The superior vena cava allows an electrode to be conveniently positioned intravascularly in an area that, when paired with another distally located electrode, encompasses a large area of the heart therebetween. Such placement is desirable because defibrillation/cardioversion is more effective when large portions of the heart are covered by the shock. To include such an electrode in the system of Anderson et al. would have been considered a matter of obvious design dependent upon the particular arrhythmias associated with the individual under treatment. An individual suffering from bouts of fibrillation and tachycardia would necessarily benefit from a system capable of both pacing and defibrillating.

Regarding the capability recited in claim 59 of selecting various sensing electrode combinations, those of ordinary skill in the art would have seen the obviousness of including any combination of available electrodes for sensing the evoked response, provided such a combination does not violate the basic principle of operation taught by Anderson et al. (i.e., that the same electrodes used for pacing not be used for sensing). One would expect the selection of any electrode set not involved in pacing to produce the predictable result of reducing afterpotential effects on the sensing amplifier with reasonable success since they are relatively isolated from the shock. The particular combination of electrodes chosen to best reduce this effect would have been considered a matter of routine optimization given the limited number of

possible combinations and given the fact that it is well-known to alter electrode configurations in pacing and defibrillation devices based on electrode performance.

5. Claims 56-59 and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silvian (Pat. No. 4,991,583) in view of Anderson et al..

Regarding claim 64, Silvian discloses a method of automatically determining whether an electrical stimulus evokes a response in the heart when the stimulus is applied by a cardiac electrical stimulation system having atrial and ventricular leads, a pulse generator, and a sensing circuit (see col. 2, lines 28-36, col. 7, lines 1-34, Fig. 4, etc.),

said method comprising the steps of:

(a) providing an electrical stimulus to at least one of an atrium or ventricle of a heart (basic pacer operation as clearly detailed throughout the reference);

(b) attenuating afterpotential associated with said electrical stimulus (see col. 4, lines 14-28 and the text abridging cols. 7 and 8, for example);

(c) selectively sensing an evoked response by the heart to the electrical stimulus, wherein a signal associated with an evoked response from the electrical stimulus is sensed between electrodes selected from the group, including atrial electrodes and ventricular electrodes of said leads (again note col. 4, lines 29-41 and the various figures showing atrial and ventricular electrodes); and

(d) wherein said atrial lead includes an atrial tip electrode and an atrial ring electrode, and said ventricular lead includes a ventricular tip electrode and a ventricular ring electrode (see Fig. 3).

While Silvian does not discuss the selection of one atrial electrode and one ventricular electrode in step (c), Silvian does disclose that by using electrodes removed from the stimulation site, one can reduce the amount of crosstalk (see for example col. 2, lines 19-36 and col. 4, lines 29-41, etc.) thus enhancing capture detection. Anderson et al. disclose a similar system wherein it is taught that crosstalk or afterpotentials can be reduced by employing a sensing electrode configuration involving atrial and

ventricular ring electrodes (note for example col. 4, lines 9-31). Clearly one of ordinary skill in the art would have seen the obviousness of selecting atrial and ventricular electrodes for sensing an evoked response. Afterpotential attenuation was a recognized problem in the art as evidenced by both Silvian and Anderson et al., and both artisans teach solutions that require distancing the sensing electrodes from the stimulation electrodes. Given that the selection of atrial and ventricular sensing electrodes does not violate the teachings of Silvian, and in fact echoes such teachings, those of ordinary skill in the art would have pursued the known potential solution proffered by Anderson et al. with a reasonable expectation of success.

While Silvian does not disclose the use of a ventricular lead comprising a coil electrode, it is taught that the particular type of lead selected is not critical to the invention (see col. 5, lines 8-16). Clearly the use of leads with coil electrodes are old and well known in the art. The examiner takes Official Notice to this effect. Coil electrodes provide greater surface areas and thus are suitable for use in high energy defibrillation systems. Depending on the individual under treatment, a lead combining both tip, ring and coil electrodes may be necessary when it is desirable to combine pacing with defibrillation. Such leads and devices are ubiquitous in the cardiac therapy arts.

Related comments apply to claims 65 and 66.

Specifically regarding claims 65 and 59, the examiner takes Official Notice that the use of superior vena cava electrodes in pacing/defibrillating systems is old and well-known. The superior vena cava allows an electrode to be conveniently positioned intravascularly in an area that, when paired with another distally located electrode, encompasses a large area of the heart therebetween. Such placement is desirable because defibrillation/cardioversion is more effective when large portions of the heart are covered by the shock. To include such an electrode in the system of Silvian would have been considered a matter of obvious design dependent upon the particular arrhythmias associated with the individual under treatment. An individual suffering from

bouts of fibrillation and tachycardia would necessarily benefit from a system capable of both pacing and defibrillating.

Specifically regarding claim 66, the examiner considers the afterpotential attenuation means of Silvian to be equivalent to that disclosed by the applicants because of its similar intended use to reduce the affects of the coupling capacitor on sensing circuitry by reducing the charge thereon.

Response to Amendment

6. The Terminal Disclaimer received December 18, 2007 has been approved. The rejection of claims based on obviousness-type double patenting has been removed.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KJS
January 11, 2008

KENNEDY SCHAETZLE
PRIMARY EXAMINER